

REMARKS

Claims 1-46 are pending for the Examiner's review, of which claims 20, 23, 24, 30, 32, 34, 35, 39, and 42-45 are presently withdrawn from consideration. While the withdrawal of claims 23 and 39 is presently traversed, these are indicated in the amendments to the claims above as being withdrawn for consistency with the office action. Claims 12, 14, 16, 25 and 41 are presently amended, and claim 46 is added. New claim 46 is fully supported by the originally-filed specification and drawings. It is also noted that citations to the specification of the present application herein are made to the published application for convenience.

In the office action, claims 23 and 39 were indicated as being withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to non-elected Species D for having a suture connection. This withdrawal is respectfully traversed, however, because elected Species H, shown in Figs. 18 and 19, specifically provides suture openings 170 that are disclosed in the specification as being provided "to thread a suture therethrough or to pass another retaining member between the contacting portions 156 to retain the unit assembled." (Application at [0060].) Additionally, it is clear that contacting members 156 have openings that are the same as openings 88 and would have been understood by one of ordinary skill in the art at the time of filing to be provided for the same reason as these openings in the embodiment of Fig. 8. Consequently, claims 23 and 39 are properly included in the elected Invention I and Species H, and should be considered in the present application.

Claims 1-19, 21, 22, 25, 36-38 and 40 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,932,975 to Main ("Main"). Claim 1 is directed to an arthroplasty prosthesis with an articulation member supportively associated with bone contacting members to allow translational movement that is substantially uncoupled from pivotal movement between bone contacting members. Regarding claims 1-12, the rejection contains the assertion that Main discloses an arthroplasty prosthesis comprising a first upper bone contact member 11, a second lower bone contact member 11, a central articulation member that allows for pivotal and translational movement of each contact independently, and a body prosthetic portion 22. The office action asserts that the central articulation member of Main comprises the inner elements located between the bone contact members.

With respect to claim 1, Main fails to teach an articulation member that is configured to permit translational movement that is substantially uncoupled from pivotal movement. Main teaches a prosthetic vertebral body including a pair of rigid housings, each of which includes a suspension plate 20 surrounded by an elastomeric suspension medium 40. A connecting structure is attached. The outline of the plate is slightly smaller than the inside of the cavity to allow "a tipping action" as well as torsional movement of the plate (Main, 3:7-45), and compression and expansion along the spinal axis (Main, 3:45-59). The elastomeric material functions as a suspending medium for the plate within the housing and exerts forces that tend to restrain and cushion relative movement of the plate and housing. (Main, 3:51-53.)

Any translational motion permitted in the device of Main is not substantially uncoupled from the pivotal movement of the plate within the housing. Because any pivoting and translational movement permitted are both restrained by the elastomeric medium, any pivoting or translational movement would deform and compress parts of the elastomeric medium and likely expand others, resisting movement along other axes. For instance, any permissible translation of the suspension plate 20 would compress the elastomeric medium on the side towards which it is displaced and allow the elastomeric medium on the opposite side to either expand or come out of contact from the suspension plate 20. This would cause the compressed side of the elastomeric medium to interact differently with the adjacent side of the suspension plate 20 than the opposite side, most likely resisting its pivoting more than the opposite side, thus causing a coupling of the translational and pivotal movements. Moreover, due to the resistance to both pivoting and translation by the elastomeric medium, a translating force on the suspension plate stem 20a would be resisted by the elastomeric medium and a coupled pivoting would result.

By contrast, the prosthesis of claim 1 provides substantially uncoupled translational and pivotal movement. For instance, the embodiment of Fig. 18 has an articulation member that both permits and restricts the claimed pivoting and translating motions in a manner that they are substantially uncoupled, with movement about one axis not inducing movement about another. (*See* Application at [0049].) Because any translational motion permitted by Main would be coupled to the pivoting motion within the device, Main does not anticipate or suggest the invention of claim 1.

With respect to claim 11, Main fails to teach or suggest an articulation member comprising first and second articulation portions articulably associating a body prosthetic portion

with each of first and second contacting members, respectively. Although the housing/plate structure 11,20 of Main permits articulation between the bone contacting portions 11b of housing 11 and the connecting structure 22, Main fails to teach an articulation member including two articulation portions, as required by claim 11. Such an arrangement is shown in Fig. 19 of the present application, and includes a pair of articulation portions 48,49 forming articulation members, each allowing for uncoupled pivotal and translational movement. Because Main fails to teach first and second articulation portions, claim 11 is further patentable over Main. Additionally, claim 40, as presently amended, recites upper and lower articulation members, each having two articulation portions. Accordingly, claim 40 is allowable for the same reasons set forth with respect to claim 11. New claim 46 depends from claim 40 and further recites that both of the disk prosthetic portions include bone contacting members configured for engaging opposing articulated bones. Claim 46 is also believed to be patentable over Main at least because it depends from claim 40.

Claim 12 is amended herein to recite that the articulation portions are in sliding contact with each other. The individual plates of Main, which the office action appears to assert are analogous to the claimed articulating members, are spaced apart by the connecting structure 22 and cannot be said to be in sliding contact with one another. Nothing else within Main discloses articulating members that are in sliding contact with each other. Accordingly, Main does not teach or suggest claim 12. Further, because nothing within the cited art teaches or suggests mutually slideable articulation members, claim 12 is not obvious over any of the cited references, either alone or in combination.

With respect to claims 13-15, the office action contains the assertion that Main also discloses that the bone contacts include protrusions 11a that extend in to the groove/recesses of the articulation portions 20. First, it is respectfully asserted that these claims are allowable at least because they depend from claim 12, which has been shown to be allowable. Additionally, claim 13 is amended herein to recite that the protrusion extends generally along an axis extending between the bone contacting members. As shown in Fig. 1 of Main, on the other hand, the portion of the housing indicated by reference 11a extends perpendicularly to the spinal axis. Moreover, portion 11a does not extend along an axis at all; rather, it is annular in shape, as shown in Fig. 4. Claim 15 additionally recites that the protrusion is tapered along the spinal axis,

whereas portion 11a is not tapered. Consequently, claims 13 and 15 are also allowable on their own merits.

The office action further asserts that, regarding claims 16-19, Main discloses a blocking member 31 that comprises annularly extending key thread portions having upper and lower edges that engage the inside thread recesses of both the upper and lower articulation portions 20. The annularly extending key thread portions of Main are a part of a threaded hole in plate 20 that receives the connector 31. (Main, 4:38-48.) The interaction between the threaded hole and the connector 31 is such that turning of the screw adjusts the distance between the housings 11'. There is no teaching in Main regarding using this structure to limit translational motion between first and second articulation portion. Further, because the threaded portions of the plate and connector of Main are used to adjust the distance between the respective plates, no translational motion between the threads is permitted, as required by claim 16. Therefore, claim 16, as well as claim 17, which depends therefrom, are patentably distinct over Main.

The office action further contains the assertion that, with respect to claims 21 and 22, Main discloses that the contact member comprises a retaining member 15 extending within the groove of the upper and lower articulation portions. Claim 21, however, recites that the first and second articulation portions are ring shaped with a hollow center. Nothing within Main teaches or suggests this feature. Accordingly, claim 21 is patentable on its own merit. It is noted that claim 21 has been amended to depend from claim 12, rather than claim 11. Accordingly, claim 21 is also believed to be allowable at least because it depends from claim 12.

Claim 41 was rejected in the office action over U.S. Patent No. 5,827,328 to Buttermann. Claim 41 has been amended to depend from claim 12, which is believed to be allowable. Therefore, claim 41 is asserted as being allowable at least because it depends from claim 12.

With respect to claims 23 and 39, the restriction of which is traversed above, nothing within Main teaches or suggests the use of a suture as a retaining member, and there is no reason to add a suture to retain any part of the device in association with another part thereof. Therefore, claims 23 and 39 are also allowable of their own merit.

With respect to claim 36, nothing within the office action asserts that Main teaches making at least one of the contacting members and the articulating members from a

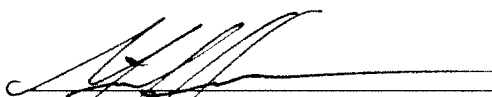
radiolucent material. Moreover, nothing within Main teaches or suggests the use of a radiolucent material. Accordingly, claim 36 is allowable over Main.

Claims 26-29, 31 and 33 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,258,031 to Salib, et al. ("Salib"). This rejection includes the assertion that Salib discloses an arthroplasty prosthesis having a first upper bone contact member 20, a second lower bone contact member 22, central articulation members 24 and 44, and diagonally oriented first and second fastener mount holes 40. The mere fact that Salib shows diagonally-oriented first and second fastener mount holes, however, does not mean that they are in a position for attaching the fastener through the apophyseal ring, as defined by claim 26. Fig. 3 of the present application shows an example of an appropriate position for a fastener mount portion for attaching a fastener from the attachment portion to the apophyseal ring. Because the apophyseal ring is located around the bottom edge of the vertebra facing the space previously occupied by the previous intervertebral disk, as shown in this figure, in such a position the fastener enters the mounting portion from that space. The bone contacting portions 156 of Figs. 18 and 19 have a similar structure to those shown in Fig. 3. The figures of Salib all show the screw entering the vertebra from well above the previous disk space and extending into the vertebra well above the location of the apophyseal ring. Accordingly, Salib does not anticipate or suggest claim 26.

In view of the foregoing, the entire application is now believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application.

Respectfully submitted,

January 14, 2008
Date


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